HHS Privacy Impact Assessment (PIA)

Date of this Submission (MM/DD/YYYY): **11/18/2003**

HHS Agency (OPDIV): **CMS**

Title of System or Information Collection: **Health Care Quality Improvement Systems (A system family containing 5 systems)**

Is this System or Information Collection new or is an existing one being modified? **Existing**
Identifying Numbers (Use N/A, where appropriate)

Unique Project Identifier Number: **N/A**

System of Records Number: **09-70-9002, 09-70-1517, 09-70-1518, 09-70-1519, 09-70-0520, 09-70-0531, 09-70-6002, 09-70-0067, 09-70-0036, 09-70-0068, 09-70-0045, 09-70-0049, 09-70-0063, 09-70-0051, 09-70-0050, 09-70-0057, 09-70-0039, 09-70-0058, 09-70-0040, 09-70-0046, 09-70-0069, 09-70-0059, 09-70-0053, 09-70-0042, 09-70-0048, 09-70-0022, 09-70-0030, 09-70-0033, 09-70-0052, 09-70-0066.**
OMB Information Collection Approval Number and Expiration Date: **0938-0581, expires 09/30/2004**

Other Identifying Number(s): **N/A**
Description

1. Provide an overview of the system or collection and indicate the legislation authorizing this activity.
The CLIA Data System was established to administer the CLIA laboratory certification program under section 353, Public Health Service Act. The law requires that all laboratories testing human specimens must complete a CLIA application form (CMS-116) and pay a user fee for a CMS–issued Certificate which authorizes the laboratory to operate, and bill Medicare or Medicaid for tests.
The Health Care Quality Improvement Systems (HCQI) comprises of three Major Applications that collect information and operate within QNet network infrastructure:

- **Standard Data Processing System (SDPS)**
- **Consolidated Renal Operations in a Web-Enabled Environment (CROWN)**
- **Quality Improvement Evaluation System (QIES)**

The Standard Data Processing System (SDPS) consists of many data and reporting requirements and was designed and developed in response to the ongoing information requirements of the Quality Improvement Organizations (QIOs) and other affiliated partners, such as the Clinical Data Abstraction Centers (CDACs) to fulfill their contractual requirements with CMS. This system, which became operational in May 1997, interfaces with CMS Central Office, 53 QIOs and CDACs.

Information resides primarily at QNet Complex 2 located at the Iowa Foundation for Medical Care (IFMC) Data Center located in West Des Moines, Iowa on dedicated QNet servers and networks. In addition, the claims warehouse resides at Complex 1, CMS Data Center in Baltimore, Maryland on dedicated QualityNet servers and networks.

Systems included under the umbrella of SDPS are:

- **Analytical Reports (OLAP)**
- **Case Review Information System (CRIS)**
- **Claims Warehouse**
- **Clinical Abstraction Tracking System (CATS)**
- **Enrollment Data Base (EDB)**
- **MedQIC**
- **Online Access Request System (OARS)**

- **Program Activity Reporting Tool (PARTner)**
- **Program Resource System (PRS)**
- **QIO Analytical Files**
- **QIO Clinical Data Warehouse**
- **QIOnet**
- **QNet Exchange (QE)**
- **QNet Quest**

Significant Legislation and Regulation of the SDPS Program
This legislation is under Title XI of the Social Security Act, Part B, as amended by the Peer Review Improvement Act of 1982.
Section 1902 (a)(30)(A) of the Social Security Act (the Act) requires that State Medicaid Agencies provide methods and procedures to safeguard against unnecessary utilization of care and services and to assure "efficiency, economy and quality of care." Under section 1902 (d), a State can contract with a PRO or PRO-like entity to perform medical and utilization review functions required by law. The contracts must be consistent with the PRO legislation. Section 1903 (a)(3)(C) of the Act specifies that 75% Federal Financial Participation is available for State expenditures for the performance of medical and utilization reviews or external quality reviews by a PRO, or by entity, which meets the requirements of section 1152 of the Act (i.e., "PRO-like entity").
Section 1902 (a)(30)(C) of the Act requires the performance of an annual, independent, external review of the quality of services furnished under each State contract with a Managed Care Organization (MCO) that is governed by section 1903 (m) of the Act. Section 1902 (a)(30)(C) further specifies that only three types of organizations are permitted to perform this review: 1) a PRO that has a contract with the Secretary to perform Medicare reviews; 2) an organization which is determined by the Secretary to meet the requirements for qualifying as a PRO contained in section 1152 of the Act (i.e.; a PRO-like entity); and 3) a private accreditation body.
The Balanced Budget Act of 1997 created section 1932 (c)(2) of the Act, which would replace section 1902 (a)(30)(C) with a new requirement for annual, external quality review (EQR) of Medicaid MCOs. In this new requirement, States are no longer restricted to using PRO, PRO-like and accrediting organizations to perform EQR; States may contract with "qualified, independent" entities. CMS has specified requirements for qualifications and independence in a Notice of Proposed Rulemaking, published on December 1, 1999. When this rule becomes final, the PRO-like designation will no longer have any applicability to statutory requirements for this annual, independent, external review of Medicaid MCO quality.

The Consolidated Renal Operations in a Web-enabled Network (CROWN) will facilitate the collection and maintenance of information about the Medicare End Stage Renal Disease (ESRD) program.

CROWN is being developed to modernize the collection and retrieval of ESRD data in a secure, Web-enabled environment. The new capabilities will allow dialysis facilities to enter information electronically and transmit it to the appropriate ESRD Network, and CMS also will be able to send feedback to the Networks and the facilities through the new environment. CROWN consists of the following major modules:

- **The Vital Information System to Improve Outcomes in Nephrology (VISION), which will support electronic data entry and encrypted transmission of ESRD patient and facility data from dialysis facilities.**
- **The ESRD Standard Information Management System (SIMS), supports the business processes of the ESRD Network Organizations.**
- **The Renal Management Information System (REMIS) which determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access ESRD patient and facility information.**

Significant Legislation and Regulation of the ESRD Network Program
The ESRD Program was established in 1972 pursuant to the provisions of 299I, Public Law 92–603. Notice of this system, ESRD/PMMIS was published in a Federal Register at 53 FR 62792 (Dec. 29, 1988), 61 FR 6645 (Feb. 21, 1996) (added unnumbered SSA use), 63 FR 38414 (July 16, 1998) (added three fraud and abuse uses), and 65 FR 50552 (Aug. 18, 2000) (deleted one and modified two fraud and abuse uses).
October 30, 1972 -Section 2991 of PL 92-603 • **Extended Medicare Coverage to individuals less than 65 years with permanent kidney failure** • **Limited reimbursement to treatment centers which meet requirements** • **Required minimal utilization rate** • **Established MRB to screen appropriateness for initiation of services**
June 29, 1973 -*Federal Regulation* • **"Interim Regulations" for implementing ESRD Program**
June 3, 1976 -*Federal Regulation* • **Patient eligibility and entitlement** • **Facility qualification or certification** • **Established ESRD Networks** • **Facility reimbursement** • **Home dialysis** • **Claims processing**
June 13, 1978 -*ESRD Amendments of PL 95-292* • **Amended Title XVIII of the Social Security Act, by adding Section 181 establishing ESRD Networks**
October 19, 1978 -*Federal Regulation* • **Added requirements related to self dialysis services**
April 7, 1986 -*PL 99-272, Consolidated Omnibus Reconciliation Act* • **Required Secretary to maintain Network Organizations** • **Permitted the Secretary to consolidate Network Organizations to 14**

Significant Legislation and Regulation of the ESRD Network Program
August 26, 1986 - *Federal Regulation* • **"Interim Regulations" for implementing ESRD Program** • **Patient eligibility and entitlement** • **Facility qualification or certification** • **Facility reimbursement** • **Home dialysis** • **Claims processing**
October 21, 1986 -*PL 99-509, Omnibus Budget Reconciliation Act* • **Required the Secretary to establish no fewer than 17 Networks** • **Funded Networks at $.50 per treatment performed** – **Revised Network responsibilities** – **Assess appropriateness of care** – **Develop criteria and standards** – **Evaluate/resolve patient grievances** – **Conduct on-site visits** – **Collect, validate, analyze data** – **Recommended sanctions**
October 2, 1987 -*Federal Regulation* • **Reorganized Networks into 18 areas**
December 19, 1989 -*PL 100-239, OBRA of 1989* • **Amended section 1881(c) of the Social Security Act to provide liability protection for Networks against disclosure of information.** • **Allowed Secretary to pool the $.50 per treatment and distribute it among Networks rather than keeping it in the area where collected.**

Quality Improvement and Evaluation System (QIES) initiative establishes CMS's goals for the standardization of the Minimum Data Set/Outcome and Assessment Information Set (MDS/OASIS) systems. QIES will provide states with the ability to collect assessment data from providers and transmit that data to a central repository for analysis and support of prospective payment systems. The QIES data management system supports a suite of applications/tools designed to provide states and CMS with the ability to use performance information to enhance on-site inspection activities, monitor quality of care, and facilitate providers' efforts related to continuous quality improvement.

QIES is a standard nationwide system and provides the following functions: receipt, authentication, validation, storage and reporting of patient, provider and survey information from multiple providers and state agencies.

QIES has to major functions. One is Survey and Certification and the second is Patient Assessment. To participate in the Medicare and/or Medicaid program, a provider must be certified and provider information is collected. Providers also agree to submit patient assessment information. The assessment portion of the system contains patient identifiable information (PII). Although the survey portion of the system contains provider information, it will also contain PII as surveyors will identify certain patient cases to be reviewed as part of the certification process.

QIES comprises of the following applications:

- **Data Collection Applications**
  - **Automated Survey Processing Environment (ASPEN)**
  - **Inpatient Rehabilitation Facility - Patient Assessment Instrument (IRF-PAI)**
  - **Minimum Data Set (MDS)**
  - **Outcome and Assessment Information Set (OASIS)**
  - **Assessment Information (SWINGBED)**

- **Data Reporting Applications**
  - **QIES to Success**
  - **Data Management System (DMS)**
  - **MDS Qis**
  - **Intermediary Extract (RHHI & FI)**

Significant Legislation and Regulation of the QIES Program
The Long Term Care Minimum Data Set System No. 09-70-1516 was given authority for maintenance under sections 1102(a), 1819(b)(3)(A), 1819(f), 1919(b)(3)(A), 1919(f) and 1864 of the Social Security Act (the Act). **Final Rule Vol. 62, No. 246, page 67174 – 67213 on December 23, 1997, required facilities certified to participate in Medicare and /or Medicaid to encode and transmit the information contain in the MDS to the state using a format that conforms to the standard record layouts and data dictionaries. This new system of records shall contain the assessment information MDS records for each individual residing in LTC facilities that are certified to participate in the Medicare and/or Medicaid programs.**
Home Health Agency Outcome and Assessment Information Set (OASIS) System No. 09-70-9002. The statutory and Regulatory Basis for the SOR is as follows: **Sections 1102(a), 1154, 1864(m), 1861(o), 1861(z), 1863, 1864, 1865, 1866, 1871, 1891 and 1902 of the Social Security Act authorize the Administrator of CMS to require HHAs participating in the Medicare and Medicaid programs to complete a standard, valid, patient assessment data set; i.e., the OASIS, as part of their comprehensive assessments and updates when evaluating adult, non-maternity patients as required by section 484.55 of the Conditions of Participation.**
Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI) System No. 07-

Significant Legislation and Regulation of the QIES Program
90-1518. The statutory and Regulatory Basis for the SOR is as follows: Section 1886 (j) (2) (D) of the Social Security Act authorizes the Secretary to collect the data necessary to establish and administer the payment system.
ASPEN Complaints/Incidents Tracking System (ACTS) System No. 09-70-1519. The statutory and Regulatory Basis for the SOR is as follows: Section 1864 of the Social Security Act (the Act) states the Secretary may use State agencies to determine compliance by providers of services with the conditions of participation. Under section 1864(a) the Act, the Secretary uses the help of State health agencies, or other appropriate agencies, when determining whether health care entities meet Federal Medicare standards. Also, section 1902(a)(9)(A) of the Act requires that a State use this same agency to set and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State use the agency utilized for Medicare or, if such agency is not the State agency responsible for licensing health institutions, the State use the agency responsible for such licensing to determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary. The State survey agencies perform both Federal certification and State licensure functions, including the investigation of complaints and entity-reported incidents. Sections 1819(d) and 1919(d) of the Act require licensure under applicable State and local laws.
Sections 1864 (c) and 1865 of the Social Security Act provides the basis for conducting complaint surveys of accredited hospitals and establishes the basic framework of complaint surveys for virtually all other accredited providers and suppliers. Regulations authorizing such surveys are found in 42 CFR 488.7(a)(2). 42 CFR 488.332 authorizes investigation of complaints of violations and monitoring of compliance. 42 CFR 488.335 authorizes actions on complaints of resident neglect and abuse, and misappropriation of resident property for nursing homes. 42 CFR 482.13(f) requires a hospital to report any death that occurs while a patient is restrained or in seclusion for behavior management, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. 42 CFR 483.13 also requires nursing homes to ensure that all alleged violations involving mistreatment, neglect, abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures, including to the State survey and certification agency. Section 353 of the Public Health Service Act (42 U.S.C. 263a) authorizes collection of information from any person or entity seeking certification under CLIA.

2. Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The CLIA program collects two pieces of personally identifiable information (PII) in order to administer the law: 1) Lab Director name – for inclusion on the printed lab certificate, and 2) Federal Tax ID Numbers (TINs) of the Lab – for transmission to Medicare and Medicaid claims payors, who are legally required to report insurance payments and the TINs of recipients to the IRS on a 1099 form. These two PII items are only in rare instances for the same individual. The above two functions cannot be performed with any less data.

The Standard Data Processing System (SDPS) consists of many information and reporting requirements and was designed and developed in immediate response to the ongoing ADP requirements of the various Quality Improvement Organizations (QIOs) and other affiliated partners, such as the Clinical Data Abstraction Centers (CDACs) to fulfill their contractual requirements with CMS.

Patient and provider level information are collected into the following systems from the providers, vendors, and QIO users.

- **Analytical Reports (OLAP): contains summarized data for payment error rates by state and nationally. The source of the data from which the summary rates are calculated is a combination of claims, case review, medical record abstractions, and payment information already stored within the SDPS data systems.**
- **Case Review Information System (CRIS): collects and stores data related to the tracking of medical records, case review information, helpline and beneficiary complaint information processed by QIOs as mandated, for identified beneficiary claims. Additional use of the tracking portion of the system supports project data collection for quality improvement work by QIOs as mandated by the QIO program.**
- **Claims Warehouse: contains both raw and rolled up Part A and Part B claims for beneficiaries. Claims are retained for a minimum of 42 months prior to being rolled off, except when connected to case review or a beneficiary complaint, which are retained indefinitely.**
- **Clinical Abstraction Tracking System (CATS): contains medical record identification information as well as tracking information for abstraction of surveillance data, ultimately measuring the success of the work of the QIOs in quality improvement work as mandated by the QIO program.**
- **Enrollment Data Base (EDB): contains beneficiary demographic information for all Medicare beneficiary enrollees, and acts as the central repository of information for all SDPS systems relating directly to beneficiaries.**
- **MedQIC: clearinghouse of information related to quality improvement information, tools, and techniques. Accessible via an Internet site to providers seeking assistance or information on improving quality of care for targeted topics within their facility. Contains no information specific to providers, beneficiaries, or claims.**
- **Online Access Request System (OARS): contains security access information for all users of the SDPS systems. Highly secure with role-based access only through an application. Controls the access to information across all SDPS data systems.**

- **Program Activity Reporting Tool (PARTner): contains information related to QIO activities for the 7th SoW. Each Task within the SoW tracks unique information as required, but includes provider specific activities performed by the QIOs in their quality improvement activities mandated by the QIO program.**

- **Program Resource System (PRS): contains reference data regarding providers from various healthcare settings, and acts as the central repository of information for all SDPS systems relating to providers. Additionally, information tracked by provider by QIOs as mandated, includes contact telephone and address information, and indicators for provider-vendor authorizations for QIO Clinical Data Warehouse data submissions and Public Reporting Initiative intentions.**
- **QIO Analytical Files: individual QIOs maintain data for analytical purposes to support quality improvement collaborative efforts with providers within their jurisdiction as mandated by the QIO program. This data resides on local database servers, securely contained within their SDPS local area network.**
- **QIO Clinical Data Warehouse: contains detailed abstracted medical record data related to both CMS-mandated data collection for surveillance, as well as data collected and submitted by providers or their authorized vendors for the purpose of voluntary Public Reporting of core measures or for provider-based quality improvement activities. Direct access to the warehouse is limited to QIO personnel only for providers in their state only, but secure, provider-specific reporting is available via the secure QNet Exchange web site for access by providers for local use, and for comparison to state and national rates.**
- **QIOnet: contains information, training materials, memos, documentation related to the SDPS system in general, and links to the Program Progress Reports (PPR) application that provides predefined reports via secure, role-based access to data in the SDPS systems. The QIOnet site sits on the closed SDPS wide area network, with its primary user base being the QIOs and CMS CO and ROs.**
- **QNet Exchange (QE): contains encrypted datasets transmitted via this CMS-approved secure transmission web application. Users include hospitals, vendors, and QIOs nationwide, transmitting data to national repositories such as the QIO Clinical Data Warehouse.**
- **QNet Quest: contains questions posed by end users of SDPS supported systems, and corresponding answers from qualified, authorized responders. Used as a resource of information for frequently asked questions as well as policy clarifications for information collected by or reported from SDPS systems.**

The Consolidated Renal Operations in a Web-enabled Network (CROWN) will facilitate the collection and maintenance of information about the Medicare End Stage Renal Disease (ESRD) program, as follows:

VISION provides a electronic data entry and reporting system for the nearly 4000-dialysis facilities in the United States.

The information stored in VISION is collected by the ESRD dialysis facility or transplant unit and submitted to the ESRD Networks via Quality Net Exchange. The data collected via the VISION tool is mostly patient registry data to track the patients through their dialysis treatments and transplants. The VISION system also collects some Quality Improvement data via the Clinical Performance Measures tool that will be rolled out this spring. Currently, there are about 135 facilities out of 4600 facilities nationally that are using this system.

ESRD Forms and Data Available for Submission with VISION consists of the following:

- **Facility information**
    - **"Facility Master" data including location, number of stations, dialysis services offered, as well as personnel names, credentials, and job titles.**
- **Patient related information**
    - **"Patient Master" data including current address and demographics.**

- **"Patient Events" such as New Patient, Transfer In, Restart, etc.**
- **CMS-2728 form: End Stage Renal Disease Medical Evidence Report, Medicare Entitlement and/or Patient Registration.**
- **CMS-2746 form: ESRD Death Notification.**
- **CMS-820 and CMS-821 Clinical Performance Measures Data Surveys.**

SIMS focuses on the mission critical operations of the ESRD Networks. These operations have been categorized into 5 major areas.

- **Form Entry/Submission and Tracking**
- **Reporting**
- **Administration**
- **Database Utilities**
- **Other SIMS Features**

Data from VISION is uploaded via Quality Net Exchange to the ESRD Networks. The ESRD Networks import this data into their local SIMS System and perform additional validation and edit checks on the integrity of the data. SIMS, in addition to the patient registry data, also houses clinical data such as vascular access information, and in the near future, electronic laboratory data. Currently, SIMS is used by all employees at every ESRD Network to which all 4600 dialysis facilities and transplant facilities report.

More specifically SIMS provides for:

- **2728/2746 - Data entry, validation and queuing of CMS-2728 and CMS-2746 forms for electronic submission to CMS.**
- **2744 - Automatic generation of CMS-2744 forms based on the patient event tracking data. The preliminary CMS-2744, with accompanying reports, can be sent to facilities for verification before the final CMS-2744 forms are submitted to CMS electronically.**
- **CMS-820 and CMS-821 Clinical Performance Measures Data Surveys.**
- **Patient Demographics - Data entry and reporting of patient demographics for annual incidence and prevalence reporting and ability to produce mailing labels for all patients.**
- **Patient Events - Data entry and reporting of a database for tracking significant patient events, including transfers in and out as well as other losses and gains to the patient populations of facilities, and changes in patient modality and transplant status.**
- **Facility Information - Data entry, management and reporting of facility information, including physical and mailing addresses, phone and fax numbers, services offered, etc. of facilities in the Network. SIMS will also provide for data entry, management and reporting of key staff members of the facilities in the Network, including alternate address (e.g. for people preferring to receive mail at home), job category, kinds of mailings to be sent.**
- **Grievances/Contacts - ESRD patients and/or their representative contact the Network seeking assistance with several issues such as quality of care problems, request for information, personnel issues, treatment options, and communication difficulties. A method of tracking and categorizing these beneficiary concerns will be defined and uniformly tabulated.**
- **Quality Improvement Projects - A revolutionary new system will be introduced for the tracking of QIP projects among internal staff, CMS staff and regional CMS project officers. Users will be able to design their QIP project and establish a "workflow" that includes approval processes and the ability to attach documents that can be modified. Users will be alerted of QIP work that has been assigned to them via use of an "inbox", and the program tracks the progress of the project. Users that are not part of the workflow will be allowed to run reports and see work in progress.**
- **SIMS will provide a flexible query facility, allowing SIMS users to view, report on or export a subset of the SIMS data, for example, patients having specified age, gender, race, diabetic/non-diabetic status, dialysis modality, regional or other characteristics.**

- **SIMS will also provide data-quality management and reporting at the national level as well as the Network level. When Network data is submitted to CMS and aggregated into a national data image, inter-Network discrepancies (for example discrepancies in patient transfer data for patients who leave one Network and enter another) will be detected, corrected if possible, and reported with minimal effort.**
- **Ability to import data dumps from several other programs including PMMIS, USRDS, and UNOS. Exported data examples would include data dumps to CMS for 2728/2746 submissions and Core Indicator data. On imported data, extensive internal error and consistency checks with multiple levels of exception reporting will be addressed. And, in certain cases, automatic resolution of contradictions will be performed.**
- **Ability to export/extract patient information from SIMS for special projects into SIMS at another Network site.**

The REMIS (Renal Management Information System) is a web-based interactive database of ESRD patient and provider information located at CMS Data Center in Baltimore, MD. It is used by CMS and the renal community to perform their duties and responsibilities in monitoring Medicare status, transplant activities, dialysis activities, and Medicare utilization (inpatient and physician supplier bills) of ESRD patients and their Medicare providers. REMIS provides a central database for CMS ESRD information.

The primary function of REMIS is to determine the Medicare-covered periods of ESRD for Beneficiaries. REMIS also serves as the primary mechanism to access information housed in the Program Management and Medical Information System (PMMIS), the legislatively mandated data repository for the ESRD program.

REMIS will support and improve data collection, validation, and analysis of the ESRD patient population over its predecessor system, REBUS. It will provide timely and accurate analysis information to the ESRD Network organizations, dialysis facilities, transplant centers, and research organizations. This will be accomplished via a Web-based data administration facility and decision support system. REMIS will provide improved support for ESRD program analysis, policy development, and epidemiological research.

REMIS will allow users to view ESRD beneficiary and provider information from the eighteen ESRD Network organizations housed in the Standard Information Management System (SIMS) Central Repository. The Networks provide Beneficiary, Provider, Medical Evidence, Death Notice, and Patient Event data. This information, along with information from CMS systems of record (Medicare Enrollment Data Base, the Common Working File, and the National Claims History, and from the United Network for Organ Sharing (UNOS), is integrated via REMIS.

Quality Improvement and Evaluation System (QIES) initiative comprises of the following applications and information collection activities:

- **The ASPEN system, including ACTS, gathers data from RO, State regulatory agencies and their surveyors related to Survey & Certification activities for Medicare and Medicaid-certified Home Health Agencies (HHA) and Long Term Care (LTC) facilities, End Stage Renal Disease (ESRD) facilities, Portable X-ray Suppliers (XRAY), Outpatient Physical Therapy/Speech Pathology Services (OPT/SP), Rural Health Clinics (RHC), Comprehensive Outpatient Rehabilitation Facilities (CORF) and Hospitals. CMS Central and Regional Office and state agency staff members use ASPEN for approval of surveys and certifications.**
- **The DMS system allows review and reporting of MDS and OASIS assessments and resident and provider data by CMS Central and Regional Offices, state agencies and IFMC.**
- **The INTERMEDIARY EXTRACT system allows Rural Home Health and Fiscal Intermediaries to download information to reconcile assessments with claim data/bills.**

- **The IRF-PAI system gathers data from inpatient rehabilitation units and hospitals to determine the IRF PPS (Prospective Payment System) for each Medicare Part A fee-for-service patient admitted to an inpatient rehabilitation, swing bed or sub acute unit of another provider or a free standing rehabilitation facility.**
- **The SWING BED system gathers data from swing bed units of hospitals for PPS for Medicare Part A fee-for service patients admitted to a swing bed.**
- **The MDS system gathers information from Long Term Care (LTC) facilities for the purpose of electronic submission of data, reports, and other information to their respective State Agencies to be used for PPS and quality of care.**
- **The OASIS system gathers information from Home Health Agencies (HHA) for the purpose of electronic submission of data, reports, and other information to their respective State Agencies to be used for PPS and quality of care.**
- **The QIES To SUCCESS website provides access to reporting and data extract capabilities.**

Users of the QIES applications include: CMS Central and Regional offices, State Agencies, Medicare and/or Medicaid certified LTC facilities, Home Health Agencies, Swing Bed Facilities, Inpatient Rehabilitation Facilities and Quality Improvement Organizations (QIOs).

3. Explain why the information is being collected.

The CLIA program collects two pieces of personally identifiable information (PII) in order to administer the law: 1) Lab Director name – for inclusion on the printed lab certificate, and 2) Federal Tax ID Numbers (TINs) of the Lab – for transmission to Medicare and Medicaid payors, who are legally required to report insurance payments and the TINs of recipients to the IRS on a 1099 form.

The Quality Improvement System for Managed Care (QISMC) standards and guidelines are key tools for use by CMS and States in implementing the quality assurance provisions of the Balanced Budget Act of 1997 (BBA), as amended by the Balanced Budget Refinement Act of 1999. The QISMC standards and guidelines are intended to achieve four major goals:

- **To clarify the responsibilities of CMS and the States in promoting quality as value-based purchasers of services for vulnerable populations.**
- **To promote opportunities for partnership among CMS and the States and other public and private entities involved in quality improvement efforts.**
- **To develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting efforts, and send a uniform message on quality to organizations and consumers.**
- **To make the most effective use of available quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of the art.**

http://www.cms.hhs.gov/cop/2d1.asp

The Standard Data Processing System (SDPS) is a Major Application (MA) whose purpose is to provide hardware and software tools to enable Quality Improvement Organization personnel to fulfill the requirements of the QIO programs. The primary purpose of the system is to aid in the administration and monitoring of the tasks mandated by the QIO program. These tasks include:

- **Improving Beneficiary Safety and Health Through Clinical Quality Improvement" in provider settings of: a. Nursing Home; b. Home Health; c. Hospital; d. Physician Office; e. Underserved and Rural Beneficiaries; and f. Medicare + Choice Organizations (M+COs).**
- **Improving Beneficiary Safety and Health Through Information and Communications" by: a. Promoting the Use of Performance Data; b. Transitioning to Hospital-Generated Data; and c. Other Mandated Communications Activities.**

- **Improving Beneficiary Safety and Health Through Medicare Beneficiary Protection Activities" through: a. Beneficiary Complaint Response Program; b. Hospital Payment Monitoring Review Program; and c. All Other Beneficiary Protection Activities.**
- **Improving Beneficiary Safety and Health Through Developmental Activities"**

Consolidated Renal Operations in a Web-Enabled Environment (CROWN) is a Major **Application (MA) whose purpose is to facilitate the collection and maintenance of information about the Medicare ESRD program, its beneficiaries, and the services provided to beneficiaries. The major CROWN applications provide support for CMS organizational business processes by conducting activities that meet the following CMS goals for the ESRD program:**

- **Improve the quality of health care service and quality of life for ESRD beneficiaries;**
- **Improve data reliability, validity, and reporting among ESRD providers/facilities, Networks and CMS (or other appropriate agency).**
- **Establish and improve partnerships and cooperative activities among and between the ESRD Networks, Quality Improvements Organization (QIOs), State survey agencies, ESRD providers/facilities, ESRD facility owners, professional groups, and patient organizations.**

Quality Improvement & Evaluation System (QIES) is an information system that will collect provider and beneficiary-specific outcomes of care and performance data across a multitude of delivery sites (such as nursing homes, rehabilitation and long term care hospitals, etc.) for use to improve the quality and cost effectiveness of services provided by the Medicare and Medicaid programs. QIES encompasses both the evolving National/State system of patient outcome assessment data, and a redesigned and expanded Online, Survey, Certification, and Reporting (OSCAR) system, which is being rebuilt using newer technologies and functionality and expanded to include important information on Federal oversight surveys (FMS and FOSS), enforcement data, and to fully support the Administrator's Nursing Home initiative. QIES will provide:

- **Data that will enable State Survey agencies to enhance on-site inspections as well as to monitor facility performance on an ongoing basis.**
- **Information to support provider quality improvement activities and for beneficiaries and their families, and purchasers, to use when making health care facility choices.**
- **Data necessary for developing and implementing case-mix based prospective payment systems for both Medicare and Medicaid.**
- **Data required for assessing the appropriateness of services provided under case mix payment systems.**
- **Critical information that will be needed in a post-acute care payment system.**
- **Information to facilitate the development of clinical best practices and the establishment of coverage policy.**

4. Identify with whom the agency will share the collected information.

OSCAR & CLIA - CMS shares the information as follows:

i. **the Lab Director Name is not visible on any system screens or reports. It is only shared with a CMS Certificate Issuance Contractor in the form of an electronic certificate issuance file. The contractor uses this file to generate the lab's certificate.**

ii. **The Lab Federal Tax ID Number is also not visible on any screens or reports. It is only shared with the Medicare Fiscal Intermediaries and carriers through the CMS Common Working File, and with the Medicaid State Agencies through a special extract report only available to those agencies**.

Users of the SDPS data systems include: CMS Central and Regional offices, QIOs, Medicare certified inpatient providers, and authorized PMS vendors.

Any 'sharing' of this information outside of the group mentioned above can only be approved by CMS. A Data Use Agreement is submitted to CMS for approval.

http://www.cms.hhs.gov/data/requests/cmsdua.pdf

CROWN users include both internal and external entities.

Each participating ESRD facility and network will be required to have a workstation with a minimum system configuration as specified by QualityNet Exchange. QualityNet Exchange will provide the ability for ESRD Networks to securely exchange multiple types of data files such as MSWord, Excel, Text, and PowerPoint, in real-time via the Internet. These files could be used for letters, static reports, comparative clinical data, and general information.

Additionally, QualityNet Exchange will provide an interactive, secure web site that will allow End Stage Renal Disease (ESRD) Facilities to transmit electronic patient data to their corresponding ESRD Network. ESRD Networks will use the QualityNet Exchange to transmit "seed" patient databases to Facilities, receive electronic patient data files from Facilities, and provide feedback to Facilities regarding data transmission. QualityNet Exchange will be responsible for routing files to/from the appropriate ESRD Facilities and Networks and ensuring that each Facility and Network can only access their data files.

REMIS will allow users to view ESRD beneficiary and provider information from the eighteen ESRD Network organizations housed in the Standard Information Management System (SIMS) Central Repository.

Internal users:

- **ESRD Networks**
- **CMS OCSQ staff (i.e., the Analysts)**
- **Application Administrators (i.e., Supervisors, etc.)**
- **System Administrators (i.e., DBA's)**
- **Other CMS users (i.e., Actuaries)**
- **Developers (i.e., Programmers).**

External users:

- **ESRD Facilities**
- **National Institutes of Health (NIH)**
- **Health Insurance Companies (Medicare Secondary Payers)**

Information is shared with CMS on a patient level basis for all patient registry information. Key identifiers are shared so that they can be matched appropriately for Medicare coverage.

The Networks provide University of Michigan and the United States Renal Data Systems a file dump of the patient information on a quarterly basis for analysis and reporting purposes.

The SIMS data is shared between the ESRD Networks that treats a patient in their facility so that duplication of data is not needed. This data is electronically downloaded via the SIMS system by the receiving Network.

The systems interfacing with CROWN are identified along with their inputs and outputs in the following table:

System	Description	Inputs	Outputs
EDB	**Enrollment Database**	**REMIS receives beneficiary specific information, patient status, and entitlement coverage data. The EDB is the source for master patient details for Medicare Beneficiaries.**	**REMIS provides Dialysis information, Transplant information, and ESRD Coverage and Patient Status Information.**
CWF	**Common Working Files**	**CMS 382 Beneficiary Selection Form**	**No output from REMIS.**
NCH	**National Claims History**	**Billing Dialysis, Transplant and Inpatient data.**	**No output from REMIS.**
SIMS	**Standard Information Management System**	**2728 Medical Evidence Form 2746 Death Notice Form 2744 Annual Facility Survey Patient Events. REMIS will use SIMS views for Medical Evidence, Death Notice, Patient Status, and Facility Survey, Facility Certification, Address and related reference c ode information**	**SIMS Notifications**
OSP	**Office of Strategic Planning**	**None**	**Ad-Hoc Queries**
OCSQ	**Office of Clinical Standards and Quality**	**None**	**Ad-Hoc Queries**
PUFS	**CMS public Use Files**	**None**	**ESRD Renal Provider File ESRD Facility Survey File**
UNOS	**Unified Network for Organ Sharing**	**Transplant and transplant follow-up data**	**UNOS Notifications**

Users of the QIES applications include: CMS Central and Regional offices, State Agencies, Medicare and/or Medicaid certified LTC Facilities, Home Health Agencies, Rehabilitation Facilities, Swing Bed Centers and QIOs.

Any 'sharing' of this information outside of the group mentioned above can only be approved by CMS. A Data Use Agreement is submitted to CMS for approval.

http://www.cms.hhs.gov/data/requests/cmsdua.pdf

5. Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.

   OSCAR & CLIA- The information will be obtained via an OMB approved form – the CMS-116 – CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) APPLICATION FOR CERTIFICATION. The form is completed once by each CLIA lab when it applies for certification pursuant to section 353 of the Public Health Service Act (labs are required to provide an update to any information that changes after the initial submission of a CMS-116). The prospective laboratory is informed that they must complete all items on the form if they wish to be certified to perform tests under the Federal CLIA statute.

The SDPS PII information is received directly from CMS in the form of claims and EDB datasets for monthly updates to the Claims and EDB Warehouses. The original source of this information comes ultimately from providers through the submission of claims to the FIs for payment. PII information is also received from the providers. There is no contact or collection of information directly from Medicare and Medicaid patients.

For CROWN, collection of information begins at the Facility level. The two main methods of collection are hard copy and the utilization of VISION to capture information. Presently, only a small number facilities are using the VISION software to electronically enter the data that is then sent to the Networks.

The ESRD Networks still collect information from the facilities by hard copy format and then enter the information into the SIMS system at the local ESRD Network level.

The CMS 2728 form is used to establish a new patient in the ESRD system. The patient must sign this form on which the following Privacy statement is made.

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244- 1250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

For QIES, collection of information begins at the Provider level. PII information is received from the providers. There is no contact or collection of information directly from Medicare and Medicaid patients.

6. State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998).

   OSCAR & CLIA - No, it will not.

The SDPS systems do not collect data over the Internet. Children under the age of 13 do participate in the QIO program. PII information is received from the providers. There is no contact with Medicare and Medicaid patients.

The CROWN systems do not collect data over the Internet. Children under the age of 13 do participate in the ESRD program. The End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration form HCFA-2728-U3 (6-97) requires the signature for the Physician Attestation and the signature from the Patient. There is no reference to the Children's Online Privacy Protection Act of 1998.

The QIES systems do not collect data over the Internet. Children under the age of 13 do participate in the QIES program. PII information is received from the providers. There is no contact with Medicare and Medicaid patients.

7. Describe how the information will be secured.

OSCAR & CLIA - The information will be secured by both physical controls (card keys, passes, security guards) at contractor sites and the CMS Data Center, as well as by electronic controls (role based access, passwords).

The CMS QNet network infrastructure security policy is guided by Internet Communications Security and Appropriate Use Policy and Guidelines for HCFA Privacy Act-protected and other Sensitive HCFA Information, November 24, 1998.

http://www.cms.hhs.gov/it/security/docs/internet_policy.pdf

The SDPS system is a 'closed' system and consists of the following components:

- **Complex 1 located in the CMS Data Center in Baltimore, MD.**
- **Complex 2 located in the IFMC Data Center in West Des Moines, IA.**
- **Complex 3 located in Warrenton, VA.**
- **Development LAN and workstations at the IFMC SDPS complex;**
- **WAN connectivity between CMS Corporate and Regional Offices, QIOs, and AGNS. There is also connectivity to the IFMC SDPS complex.**

The IFMC SDPS test and development servers are located in the IFMC corporate data center.

SDPS workstations and servers are also located at each of the QIOs. A QIO Manual was provided to each QIO when the original system was deployed. This document details the minimum requirements for environmental controls, electrical considerations, physical space and furnishings requirements, etc.

The IFMC corporate data center is a restricted area and has appropriate environmental security controls implemented, to include measures to mitigate damage to Automated Information Systems caused by fire, electricity, water and climate changes.

SDPS Data Integrity/Validation Controls are used as follows:

- **Malicious Programs and Virus Protection - Norton Antivirus is used for virus protection and is loaded at both the server and workstation level. Definition files are updated daily and scans are done daily. Servers for the QNet Exchange and MedQIC Internet**

applications are isolated between firewalls in Complex 3 in Warrenton, VA. Data in the SDPS data systems are not directly accessible by external users, and are only reported based on stringent role-based access authorization via OARS.

- **Message Authentication – Email servers are located at Complex 3 and are maintained and the responsibility of BCSSI.**
- **Integrity – The integrity of the data is protected via edits at the application level. Data transmitted through the QNet Exchange Internet application is protected during transmission and at rest through a CMS-approved 3DES-encryption protocol in addition to SSL across the Internet.**
- **Verification – Field level edits are used in all SDPS data systems, either directly through SDPS-supported data collection tools, or through edit checking completed prior to accepting submitted files to the warehouse. Data reported out through role-based access reporting systems originates from the edited data systems within the secured network, not directly from externally submitted files.**
- **Confidentiality – SDPS message traffic is carried over the SDPS WAN and the web servers employ SSL encryption. CMS guidelines require users outside the SDPS WAN obtain permission from CMS to attach to and access information via a formal request process, which includes a Data Use Agreement (DUA).**

For access to all applications, users must complete a QNet Access Request Form, which has been automated for all but CMS RO users in the OARS system. This form specifies which system(s) the user needs access to and the level of authority for that system. (Production, test, training or development, update or read only) The user's security administrator must approve the request. Once approved through the OARS application, backend processes apply the authorizations to the appropriate systems to allow nearly real-time access for the user (within an hour or less). If completed in paper form, as is needed by the CMS ROs, the form is forwarded to the appropriate CMS CO security administrator for user id setup into the OARS system. This same process is used also for changes and deletions from all SDPS applications.

The CROWN/ESRD information is secured in several different layers.

Physical layer - the hard copy data that comes into the ESRD Networks is secured at the local levels behind locked doors and is stored in locked file cabinets.

Hardware layer – All machines that store data have a login required, have an electronic screen saver password and all the application data is protected again behind a login to the software using a secure token.

Communication layer – the entire SIMS system relies on QualityNet (QNet) network infrastructure.

The QIES system is a 'closed' system and consists of the following components:

- **Complex 1 located in the CMS Data Center in Baltimore MD.**
- **Development LAN and workstations at the IFMC QIES complex;**
- **WAN connectivity between CMS Corporate and Regional Offices, QIES State Agencies including individual state surveyors, and the QIES National Collection Site and AGNS. There is also connectivity to the IFMC QIES complex, Alpine and FU offices.**

The 53 QIES production Windows 2000 servers are located in state agencies in each of the 50 states, Puerto Rico, Virgin Islands, and District of Columbia, with most being located in state office buildings. A few state servers are located in the offices Myers & Stauffer and the Iowa, Virgin Islands and Puerto Rico servers are located at the IFMC corporate data center.

A document titled 'MDS Infrastructure Requirements' was provided to each state agency when the original system was deployed. This document details the minimum requirements for environmental controls, electrical considerations, physical space and furnishings requirements, etc. This document continues to be provided on an as needed basis. IFMC cannot address the physical and environmental protection actually afforded at any non-IFMC sites.

The IFMC QIES test and development servers are located in the IFMC corporate data center.

The IFMC corporate data center is a restricted area and has appropriate environmental security controls implemented, to include measures to mitigate damage to Automated Information Systems caused by fire, electricity, water and climate changes.

QIES Data Integrity/Validation Controls are as follows:

- **Malicious Programs and Virus Protection - QIES is not accessible via the Internet nor are email services installed on the servers. Therefore, QIES is minimally vulnerable to hackers, malicious programs and virus. McAfee Netshield and Norton Antivirus are used for virus protection. Definition files are updated weekly, at minimum, and more often if necessary.**
- **Message Authentication – No email servers exist in this system, therefore this category does not apply.**
- **Integrity – The integrity of the data is protected during transmission using 128 bit-encryption.**
- **Verification – ASPEN & ACTS– Field level edits are used in the online system. Should data be entered off-line – it is validated against the online edits during the upload process. Additional verification is used to assure that surveys did load correctly at the national database level. Indicators advise survey status to assure all surveys are completed. DMS is a view only system and verification does not apply. IRF-PAI, SWING BED, MDS and OASIS contain very detailed validation programs that include field level and relational edits to verify the accuracy of the data. QIES to Success is a reporting system only; therefore, no verification process is contained in this system.**
- **Confidentiality - QIES message traffic is carried over the CMS WAN and the web servers employ 128-bit encryption. CMS guidelines require the state agencies to obtain permission from CMS to attach to other systems via a formal request procedure. Some ASPEN surveyors participating in pilot programs with CMS are able to download survey data via encrypted transmission files. Each state and facility is provided access to their data only.**

For IFMC Employee s' access to all applications except ASPEN & ACTS, users must complete a QNet Access Request Form. This form specifies which system(s) the user needs access to and the level of authority for that system. (Production, test, training or development) The user's security manager must approve the request. Once approved, the form is forwarded to the appropriate administrator for user id setup. This same form is used for changes and deletions from these QIES applications. An IFMC system administrator grants development access for development servers. User access to the ASPEN system is controlled via the ASPEN coordinator at the state agency.

8. Describe plans for retention and destruction of data collected.
OSCAR & CLIA-Data is backed up and archived at the CMS (secure) Hot Site. Contractors are bound by CMS record security and retention policies.

CMS Information Systems Security Policy, Standards and Guidelines Handbook, Version 1, February 19, 2002, Chapter 16 establishes policy for the security of electronic mail, facsimile, and other media. It serves as the primary source of Information Technology (IT) systems security information for all CMS IT users. The policies, standards and guidelines described therein apply to all users of CMS hardware, software, information, and data. The CMS AIS Security Program ensures the existence of adequate safeguards to protect personal, proprietary, and other sensitive data in automated systems and ensures the physical protection of all CMS General Support Systems (GSSs) and Major Applications (MAs) that maintain and process sensitive data.

http://www.cms.hhs.gov/it/security/docs/handbook.pdf

9. Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.

OSCAR & CLIA-These data are not accessible by using either field or any PII as a key for record retrieval. Therefore, no System of records was obtained.

CMS has the authority to collect and use personally identifiable information that is relevant and necessary to accomplish the purpose of the agency (defined as the Department of Health and Human Services) under the provisions of the Privacy Act of 1974 (5 U.S.C. 552a). The Privacy Act requires that the agency maintain all records in system of records and inform the public of the establishment or revision of a system of record through publication in the Federal Register.

The Standard Data Processing System (SDPS)
No Systems of Records exists.
The Consolidated Renal Operations in a Web-enabled Network (CROWN)
Medicare End Stage Renal Disease (ESRD) Program
System of Records No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244- 1250 or as updated and republished.
Quality Improvement and Evaluation System (QIES)
Long Term Care Minimum Data Set - The System of Records number originally was 09-70-1516, but was changed to 09-70-1517 on February 13, 2002. The original number was a duplicate. Updates were made on 7-16-98, 8-18-00, 2-12-02.
09-70-1518 Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI)
09-70-9002 Home Health Agency Outcome and Assessment Information Set (HHA OASIS)
09-70-1519 ASPEN Complaints/Incidents Tracking System (ACTS)
Additional Systems of Records: 09-70-0531, 09-70-6002, 09-70-0067, 09-70-0036, 09-70-0068, 09-70-0045, 09-70-0049, 09-70-0063, 09-70-0051, 09-70-0050, 09-70-0057, 09-70-0039, 09-70-0058, 09-70-0040, 09-70-0046, 09-70-0069, 09-70-0059, 09-70-0053, 09-70-0042, 09-70-0048, 09-70-0022, 09-70-0030, 09-70-0033, 09-70-0052, 09-70-0066.

Endorse	**Endorse**	**Approve**
_____/s/_____	___/s/_____	____/s/_____
J. Ned Burford	Timothy P. Love	Thomas A. Scully
CMS Privacy Officer	Chief Information Officer	CMS Administrator
Date _11/21/2003_____	Date: _11/21/2003_____	Date: _11/21/2003_____